

Notice of Allowability

Application No.

09/989,481

Examiner

Christopher J Nichols, Ph.D.

Applicant(s)

CHAU, RAYMOND MING WAH

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 15 January 2004.
2. ☒ The allowed claim(s) is/are 1,6-8,12,13,15 and 35-59.
3. ☒ The drawings filed on 15 January 2004 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

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DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Response and Amendment filed 15 January 2004 has been received and entered in full.
2. All previous Objections and Rejections as set forth in the previous Office Action (8 August 2003) are hereby *withdrawn* in view of Applicant's amendments (15 January 2004).

EXAMINER'S AMENDMENT

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

In the Claims:

Claim 1 (Currently Amended) A method for promoting the survival or maintenance of mammalian motoneurons comprising administering at or near ~~to~~ the motoneurons an effective amount of a purified polypeptide comprising an amino acid sequence as set forth in SEQ ID NO:4.

Claims 2-5 (Cancelled)

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Claim 6 (Currently Amended) The method of claim 1, ~~wherein the method further comprises~~
comprising promoting regeneration of the axon of a motoneuron.

Claim 7 (Previously Amended) The method of claim 1, wherein the method comprises
promoting the survival or maintenance of neurons *in vitro*.

Claim 8 (Currently Amended) The method of claim 1, wherein the method comprises promoting
the survival, ~~growth, proliferation,~~ or maintenance of isolated spinal motoneurons *in vitro*.

Claims 9-11 (Cancelled)

Claim 12 (Currently Amended) The method of claim 1, ~~wherein the method further comprises~~
comprising promoting the ~~the~~ reinnervation of a target muscle of motoneurons in a mammal.

Claim 13 (Previously Amended) The method of claim 6, wherein the method comprises
promoting the axonal regeneration of axotomized motoneurons in a mammal.

Claim 14 (Cancelled)

Claim 15 (Previously Amended) The method of claim 1, wherein the method comprises
administering the polypeptide in a suitable carrier to a mammal for treatment of a peripheral
nerve injury.

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Claims 16-34 (Cancelled)

Claim 35 (Currently Amended) A method for promoting axonal regeneration of an axotomized motoneuron, comprising administering at or near to the motoneuron an effective amount of a purified polypeptide comprising an amino acid sequence as set forth in SEQ ID NO:4.

Claim 36 (Currently Amended) ~~The method of claim 35, wherein the method comprises~~ A method for promoting axonal regeneration of an axotomized motoneuron, comprising administering the polypeptide an effective amount of a purified polypeptide comprising an amino acid sequence as set forth in SEQ ID NO:4 to non-neuronal cells or tissues sufficiently proximal to the axotomized motoneuron such that the polypeptide is effective at promoting axonal regeneration of the axotomized motoneuron.

Claim 37 (Currently Amended) A method for promoting the reinnervation of a target muscle of motoneurons, comprising administering at or near to the motoneurons an effective amount of a purified polypeptide comprising an amino acid sequence as set forth in SEQ ID NO:4.

Claim 38 (Currently Amended) ~~The method of claim 35, wherein the method comprises~~ A method for promoting the reinnervation of a target muscle of motoneurons comprising administering the polypeptide an effective amount of a purified polypeptide comprising an amino acid sequence as set forth in SEQ ID NO:4 to non-neuronal cells or target muscle tissues

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sufficiently proximal to the motorneurons such that the polypeptide is effective at promoting the reinnervation of the target muscle.

Claim 39 (New) A method for promoting the survival or maintenance of mammalian motorneurons comprising administering an effective amount of a purified polypeptide comprising an amino acid sequence as set forth in SEQ ID NO:4 to non-neuronal cells or tissues sufficiently proximal to neurons such that the polypeptide is effective at promoting the survival or maintenance of mammalian neurons.

Claim 40 (New) The method of claim 39, further comprising promoting regeneration of the axon of a motoneuron.

Claim 41 (New) The method of claim 40, wherein the method comprises promoting the axonal regeneration of axotomized motorneurons in a mammal.

Claim 42 (New) The method of claim 39, further comprising promoting the reinnervation of a target muscle of motorneurons in a mammal.

Claim 43 (New) The method of claim 39, wherein the method comprises administering said polypeptide in a suitable carrier to a mammal for treatment of a peripheral nerve injury.

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Claim 44 (New) A method for promoting the survival or maintenance of mammalian motoneurons comprising administering at or near the motoneurons an effective amount of a purified polypeptide comprising an amino acid sequence as set forth in SEQ ID NO:3.

Claim 45 (New) The method of claim 44, further comprising promoting regeneration of the axon of a motoneuron.

Claim 46 (New) The method of claim 45, wherein the method comprises promoting the axonal regeneration of axotomized motoneurons in a mammal.

Claim 47 (New) The method of claim 44, wherein the method comprises promoting the survival or maintenance of neurons *in vitro*.

Claim 48 (New) The method of claim 44, wherein the method comprises promoting the survival or maintenance of isolated spinal motoneurons *in vitro*.

Claim 49 (New) The method of claim 44, further comprising promoting the reinnervation of a target muscle of motoneurons in a mammal.

Claim 50 (New) The method of claim 44, wherein the method comprises administering said polypeptide in a suitable carrier to a mammal for treatment of a peripheral nerve injury.

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Claim 51 (New) A method for promoting axonal regeneration of an axotomized motoneuron, comprising administering at or near the motoneuron an effective amount of a purified polypeptide comprising an amino acid sequence as set forth in SEQ ID NO:3.

Claim 52 (New) A method for promoting axonal regeneration of an axotomized motoneuron, comprising administering an effective amount of a purified polypeptide comprising an amino acid sequence as set forth in SEQ ID NO:3 to non-neuronal cells or tissues sufficiently proximal to the axotomized motoneuron such that the polypeptide is effective at promoting axonal regeneration of the axotomized motoneuron.

Claim 53 (New) A method for promoting the reinnervation of a target muscle of motoneurons, comprising administering at or near the motoneurons an effective amount of a purified polypeptide comprising an amino acid sequence as set forth in SEQ ID NO:3.

Claim 54 (New) A method for promoting the reinnervation of a target muscle of motoneurons comprising administering an effective amount of a purified polypeptide comprising an amino acid sequence as set forth in SEQ ID NO:3 to non-neuronal cells or target muscle tissues sufficiently proximal to the motoneurons such that the polypeptide is effective at promoting the reinnervation of the target muscle.

Claim 55 (New) A method for promoting the survival or maintenance of mammalian motoneurons comprising administering an effective amount of a purified polypeptide

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comprising an amino acid sequence as set forth in SEQ ID NO:3 to non-neuronal cells or tissues sufficiently proximal to neurons such that the polypeptide is effective at promoting the survival or maintenance of mammalian neurons.

Claim 56 (New) The method of claim 55, further comprising promoting regeneration of the axon of a motoneuron.

Claim 57 (New) The method of claim 56, wherein the method comprises promoting the axonal regeneration of axotomized motoneurons in a mammal.

Claim 58 (New) The method of claim 55, further comprising promoting the reinnervation of a target muscle of motoneurons in a mammal.

Claim 59 (New) The method of claim 55, wherein the method comprises administering said polypeptide in a suitable carrier to a mammal for treatment of a peripheral nerve injury.

4. Authorization for this examiner's amendment was given in a telephone interview with Margaret Churchill (Reg. No. 39,944) on 29 March 2004 (message on Examiner's voicemail).

Summary

5. Claims 1, 6-8, 12, 13, 15, and 35-59 are hereby allowed.

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6. The Examiner notes that support for the limitations “at or near the motoneuron” may be found at pp. 45 line 21 & pp. 46 lines 16-17 of the Specification.

7. The Examiner acknowledges that acceptance of the above Examiner’s Amendment does not mitigate in any way, shape, or form, Applicant’s right to pursue additional subject matter in continuation, continuation-in-part, and/or divisional applications pursuant to 35 U.S.C. §120 and §121.

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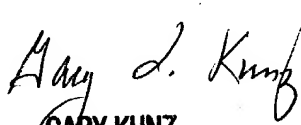
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on **(571) 272-0887**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN
March 29, 2004


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